K071299

Sponsor/ Manufacturer	Digital Healthcare Inc	AUG 3 1 2007
	Address: 343 South White Street Wake Forest NC 27587	
	Phone: 919 554 9650	
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	e-mail usinfo@digital-healthcare.com	
Contact	Mr Gerry Skews Digital Healthcare Inc	
	Address 343 South White Street Wake Forest NC 27587	
	Phone: 919 554 9650	
	Fax 919 435 5277	
	e-mail usinfo@digital-healthcare.com	
Date Prepared	April 30th, 2007	
Proposed Class	II	
Proprietary Name	***i*P®** Digital Image and Informatics Platform to include OcuLab ***i*P®** OptoMize ***i*P®** Retasure ***i*P®**	
Common Name	Clinical Imaging and Data Management Software	
Classification Name	HKI, NFF, NFG, NFT	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Digital Healthcare, Inc.
c/o Gerry Skews
343 South White Street
Wake Forest, NC 27587

AUG 3 1 2007

Re: K071299
Trade/Device Name: iP System
Regulation Number: 21 CFR 892.2050
Regulation Name: Opthalmic Image Management System
Regulatory Class: Class II
Product Code: NFJ, NFF, NFG, HKI
Dated: July 12, 2007
Received: July 16, 2007

Dear Mr. Skews:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: *i*P® Digital Imaging and Informatics Management System

Indications for use: The *i*P® system is used by health professionals to capture, store, encode, encrypt, transmit, decrypt, decode, display, process, spatially calibrate, assess, grade and report on images and data that are captured on a range of approved medical devices that include but are not limited to :

A. Mydriatic Fundus Cameras
B. Non Mydriatic Fundus Cameras
C. Scanning Laser Ophthalmoscopes
D. Optical Coherence Tomography Instruments
E. Bio Microscopes (Slit Lamps)
F. Non Radiometric Ultrasound devices
G. Video image sources
H. TWAIN compliant imaging sources
I. Compliant data sources placed in network accessible folders and directories
J. Images of known format from digital cameras and scanners
K. Electronic information complying to accepted DICOM formats
L. Other devices connected in proprietary formats

Prescription Use ___X___ (21CFR 801.109 Subpart D) OR Over the counter use _____ (21 CFR 801 subpart C)

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clay R. Butterworth

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K071299